

temporary valve being operative to effect greater antegrade flow than retrograde flow through said vessel; and

b) placing at least one temporary filter in said flowpath downstream from said cardiac valve, said filter being operative to restrict the passage of emboli while allowing blood to flow through said vessel.

2. (Withdrawn) A method for performing an operation on a cardiac valve of a heart while the heart is beating, comprising the steps of:

a) positioning at least one temporary valve in a flow path of a blood vessel downstream from said cardiac valve, said temporary valve being operative to effect greater antegrade flow than retrograde flow through said vessel;

b) resecting at least a portion of the cardiac valve; and

c) affixing at least one prosthetic valve at or downstream from said resected cardiac valve.

3. (Amended) A device for performing intravascular procedures wherein at least a portion of the device is adapted for placement in a flowpath of a blood vessel, said intravascular portion device comprising:

a) a valve means configured that acts to allow greater antegrade flow than retrograde flow through the said vessel, and said valve means positioned at the portion of the device adapted for placement in the flowpath of the blood vessel; and

b) a filter operative to restrict the passage of emboli while allowing blood flow through the vessel, and the filter positioned adjacent to said valve means at the portion of the device adapted for placement in the flowpath of the blood vessel.

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4. (Withdrawn) A device for filtering blood flowing through a vessel within the vascular system, said device comprising:

a) an expandable element operative to direct bloodflow through said vessel to a flow area of said vessel ; and b) a filter operative to filter the blood passing through said portion of said flow area.

2/5. (Amended) A device for use in intravascular procedures, wherein at least a portion of the device is adapted for placement in a flowpath of a blood vessel, the said intravascular portion device comprising:

a) a filter including a flowpath spanning portion operative to filter at least a portion of blood flowing through the said vessel, the filter including a flowpath spanning portion positioned at the portion of said device adapted for placement in the flowpath of the blood vessel; and

b) a valve assembly including valve elements and said positioned adjacent to the flowpath spanning portion of said filter at said portion of said device adapted for placement in the flowpath of the blood vessel, said valve elements being positionable in a first state away from said flowpath spanning portion to permit antegrade blood flow through the said flowpath spanning portion, and positionable in a second state adjacent to said flowpath spanning portion to prevent retrograde blood flow through said flowpath spanning portion.

6. (Withdrawn) An expandable valve for insertion into a vessel to allow greater flow along a central axis of said vessel in a first direction than in a second, opposite direction, said valve comprising:

a) an expandable member adapted for selective expansion to abut the wall of the vessel, said expandable member having at least one flow path therethrough;

b) a valve element, said valve element opening during flow through said flow path in said first direction while closing over said flow path during flow in said second direction; and wherein said expandable member and said valve element are unitary assembly adapted for insertion into said vessel in a collapsed state along an axis angularly offset from said central axis of said vessel.

7. (Withdrawn) An expandable valve adapted to be expanded to abut the interior wall of a vessel and occupy substantially all of a cross-sectional flow area of said vessel, said valve comprising:

a) a flexible, elongated element, said elongated element configured into a loop that can be collapsed to form two adjacent parallel segments mutually joined at their respective ends, and that can be expanded to a ring-like form adapted to abut the interior wall of said vessel, said loop adapted to occupy a portion of the cross-sectional flow area of said vessel;

b) a backing element affixed to and spanning said loop, said loop and said backing elements forming a valve base; and

c) at least one valve leaflet peripherally affixed to said valve base, said valve leaflet adapted in a first

state to collapse against said backing element to prevent flow in a first direction through said valve base, and adapted in a second state to move away from said backing element to permit fluid flow in a second direction through said valve base.

8. (Withdrawn) An expandable valve according to claim 7 having at least four valve leaflets.

9. (Withdrawn) An expandable valve according to claim 7 having at least two valve leaflets affixed to said valve base, said valve leaflets sized such that a combination of fewer than the total number of said valve leaflets can resist flow in a first direction through said valve base and open to allow flow in a second direction through said valve base.

10. (Withdrawn) A method for providing a valve within a tubular vascular structure, comprising:

- a) inserting an expandable valve in a collapsed state into said vascular structure through an entry site; and
- b) expanding said valve within said vascular structure to an expanded state proximate to said entry site.

11. (Withdrawn) A method according to claim 10 wherein said valve is inserted into said vascular structure along an axis transverse to a central axis of said vascular structure.

12. (Withdrawn) An expandable intravascular filter device adapted to filter blood flowing through a tubular vascular structure, said filter comprising:

a) an elongated filament, said filament having a proximal and a distal end, said distal end being adapted to be inserted into said vessel through an entry site; and

b) an expandable filter, said filter being adapted to track along said filament, said filter having a collapsed state with a relatively small maximum transverse dimension and having an expanded state with a relatively large transverse dimension, said filter being insertable into said vessel in a collapsed state and expandable in said vessel to an expanded state, wherein said filter occupies a cross sectional flow area of said vessel not occupied by said filament, said filter being attached to said filament proximal to the distal end of said filament.

13. (Withdrawn) An expandable intravascular filter kit, said kit comprising:

a) an elongated cannula having an outer diameter D and defining at least one lumen passing therethrough, said cannula having a proximal and a distal end, said distal end being adapted for insertion into a blood vessel through an entry site,

b) a filter axially and slidably positioned along a limited portion of the outer surface of said cannula near said distal end, said filter being collapsible in a first state whereby a maximum dimension of said filter and said cannula is relatively small, and thereby being adapted in said first state for insertion into said vessel and being expandable in a second state, whereby said filter extends transverse to a central axis of said cannula, thereby being adapted to span at least a portion of said vessel and to filter blood flowing therethrough.

14. (Withdrawn) An expandable intravascular filter according to claim 13 wherein said filter is circumferentially slidably positioned on said limited portion.

15. (Withdrawn) An expandable intravascular filter according to claim 12 wherein said filter includes at least one of circumferentially extending filter elements

extending from a distal end thereof, said circumferentially extending filter elements being adapted to filter blood passing therethrough along an axis transverse to a central axis of said cannula.

16. (Withdrawn) An expandable intravascular filter device according to claim 12 wherein said distal end of said cannula is selectively deflectable away from a central axis of said cannula.

17. (Withdrawn) A valve fixation device for affixing a flexible prosthetic valve to the interior wall of a vessel, said prosthetic valve having a generally cylindrical shape with a base, an apex, an interior surface and an exterior surface, said prosthetic valve further having a long axis passing through the centers of the circles formed by at least two circumferences of said cylindrical shape along the distance between said apex and said base, said fixation device comprising:

a) at least two expandable fixation rings, said rings being expandable from a first compressed state having a relatively small maximum transverse dimension to a second expanded state having a relatively large maximum transverse dimension, said rings expandable in a direction

perpendicular to the long axis of said prosthetic valve, each of said rings being affixed to said prosthetic valve near a respective end thereof.

18. (Withdrawn) A valve fixation device according to claim 17 further comprising at least one rigid strut on the exterior surface of said prosthetic valve passing along an axis parallel to the long axis of said valve, said struts being affixed to said rings at least one point on each of said rings.

19. (Withdrawn) A prosthetic cardiac valve comprising:

a) flexible prosthetic valve means having a generally cylindrical shape with a base, an apex, an interior surface and an exterior surface, said prosthetic valve further having valve leaflets joined to said interior surface, said leaflets forming commissures where two of said leaflets meet along said interior surface, said prosthetic valve further having a long axis passing through the centers of the circles formed by at least two circumferences of said cylindrical shape taken along the distance between said apex and said base;

b) at least two expandable fixation rings, each being affixed to a respective end of said prosthetic valve at least one point, said rings being expandable in a direction perpendicular to the long axis of said prosthetic valve ; and

c) at least one rigid strut on the exterior surface of said prosthetic valve passing along an axis parallel to the long axis of said valve, said struts being affixed to said rings at least one point on each of said rings.

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20. (Withdrawn) A prosthetic cardiac valve according to claim 19 comprising two expandable fixation rings and three rigid struts, each of said struts passing proximate to one of said commissures.

21. (Withdrawn) A prosthetic cardiac valve according to claim 20 wherein said struts are affixed to said prosthetic valve at least one point.

22. (Withdrawn) A prosthetic cardiac valve according to claim 20 wherein said rings are affixed to the exterior surface of said prosthetic valve.

23. (Withdrawn) A prosthetic cardiac valve according to claim 20 wherein said rings are further affixed to a sealing means for sealing against an interior surface of said vessel wall.

24. (Withdrawn) A prosthetic cardiac valve according to claim 20 wherein said struts are further affixed to a sealing means for sealing against the interior surface of said vessel wall.

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25. (Withdrawn) A prosthetic cardiac valve according to claim 20 wherein said rings have integral fixation means for securing said prosthetic valve to an interior surface of said vessel wall.

26. (Withdrawn) A prosthetic cardiac valve according to claim 20 wherein said struts have integral fixation means for securing said prosthetic valve to the interior surface of said vessel wall.

27. (Withdrawn) A method for affixing a prosthetic valve to the wall of a vessel, comprising the steps of:
a) during cardiac rhythm, inserting said prosthetic valve into a vessel in a compressed state;

b) advancing said prosthetic valve to the site of implantation;

c) expanding said prosthetic valve to an expanded state; and

d) passing at least one fixation means entirely through the wall of said vessel.

28. (Withdrawn) The method of claim 27 wherein said fixation means is passed from the inside of said vessel through to the outside of said vessel.

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29. (Withdrawn) The method of claim 27 wherein said fixation means is passed from the outside of said vessel through to the inside of said vessel.

30. (Withdrawn) The method of claim 27 wherein said fixation means is a suture.

31. (Withdrawn) The method of claim 27 wherein said method is performed during cardiac rhythm.

32. (Withdrawn) A method of replacing a native cardiac valve, comprising the steps of:

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- a) during cardiac rhythm, inserting into a vessel the distal ends of a set of two concentric cannulae including an inner cannula and an outer cannula, said inner cannula having a smaller outer diameter than the inner diameter of said outer cannula such that said inner cannula can be slidably placed within a lumen of said outer cannula;
- b) advancing the distal ends of said cannulae to a site proximate to said cardiac valve;
- c) positioning said cannula whereby the distal end of said inner cannula extends beyond the distal end of said outer cannula, and expanding an expandable member secured to an outer surface of said cannula, whereby said expandable member occupies substantially all of the cross sectional flow area of said vessel;
- d) performing a procedure on said native valve at least in part through a lumen of the inner cannula;
- e) removing said inner cannula and said expandable member through said lumen of said outer cannula, the distal end of said outer cannula remaining proximate to the attachment site of said cardiac valve to said vessel;
- f) advancing a valve prosthesis through said outer lumen of said cannula to a site at or near the attachment site of said cardiac valve; and

g) affixing said valve prosthesis to the wall of said vessel.

33. (Withdrawn) A method of repairing and replacing a stenosed cardiac valve comprising the steps of:

a) during cardiac rhythm, disrupting said cardiac valve, without completely removing said cardiac valve such that said cardiac valve no longer functions as a valve, thereby decreasing pressure drop across said cardiac valve; and

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b) implanting a prosthetic valve downstream of said cardiac valve.

34. (Withdrawn) A method of replacing a diseased cardiac valve comprising the sequential steps of:

a) during cardiac rhythm, placing a valve prosthesis into a vessel downstream of said cardiac valve; and
b) resecting at least some portion of said cardiac valve.

35. (Withdrawn) A method of replacing a diseased cardiac valve comprising the sequential steps of:

a) during cardiac rhythm, placing a valve prosthesis into a vessel downstream of said cardiac valve;

- b) resecting at least some portion of said cardiac valve;
- c) repositioning said valve prosthesis to or near the site of the resected cardiac valve; and
- d) affixing said valve prosthesis to the wall of said vessel.

36. (Withdrawn) A method of replacing a diseased cardiac valve comprising the steps of:

- a) during cardiac rhythm, inserting an expandable valve prosthesis into a vessel in a collapsed state and positioning said valve prosthesis at the site of said cardiac valve;
- b) expanding said valve prosthesis and crushing said cardiac valve against the wall of said vessel; and
- c) affixing the valve prosthesis to said vessel wall through the crushed cardiac valve.

37. (Withdrawn) A method of resecting cardiac valve leaflets attached to the inner wall of a vessel comprising the steps of:

- a) during cardiac rhythm, inserting one end of a elongated resection instrument into the vascular system and advancing said end proximate to said cardiac valve;

b) directing said end against the wall of said vessel;
c) advancing said end along the wall of said vessel
until it makes contact with a the attachment of said
leaflet of said cardiac valve to said vessel; and
d) resecting said leaflet with said resection
instrument.

38. (Withdrawn) A method of repairing a stenotic
cardiac valve comprising the steps of:

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a) during cardiac rhythm, disrupting the leaflets of
said valve such that the pressure drop across said valve is
decreased; and
b) supporting said leaflets with a valve support
device that at least in part spans the flow area of said
valve upstream of said valve leaflets.

39. (Withdrawn) A method for enabling performance of
an operation on a cardiac valve of a heart while the heart
is beating, comprising the steps of:

a) placing at least one temporary valve in a flow path
of a blood vessel of said cardiac valve, said temporary
valve being operative to effect greater antegrade flow than
retrograde flow through said vessel; and

b) placing at least one temporary filter in said flowpath downstream from said cardiac valve, said filter being operative to restrict the passage of emboli while allowing blood to flow through said vessel.

40. (Withdrawn) A method for performing an operation on a cardiac valve of a heart while the heart is beating, comprising the steps of:

a) positioning at least one temporary valve in a flow path of a blood vessel downstream from said cardiac valve, said temporary valve being operative to effect greater antegrade flow than retrograde flow through said vessel;

b) resecting or disrupting at least a portion of the cardiac valve; and

c) affixing at least one prosthetic valve at, upstream or downstream from said resected cardiac valve.

3/ 41. (Amended) A device for performing intravascular or intracardiac procedures wherein at least a portion of the said device is adapted for placement in a flowpath of a blood vessel, said device portion comprising:

a) a valve means that acts to allow greater antegrade flow than retrograde flow through said vessel, and said valve means positioned at said portion of said device

adapted for placement in the flowpath of the blood vessel;

and

b) a filter operative to restrict the passage of emboli while allowing blood flow through the said vessel, and said filter positioned adjacent to said valve means at said portion of said device adapted for placement in the flowpath of the blood vessel.

42. (Withdrawn) A device for performing intravascular or intracardiac procedures wherein at least a portion of said device is adapted for placement in the flowpath of blood, said portion comprising: a valve means that acts to allow greater antegrade flow than retrograde flow.

43. (Withdrawn) A valve fixation device for affixing a non-flexible prosthetic valve to the interior wall of a vessel, said prosthetic valve having a generally cylindrical shape with a base, an apex, an interior surface and an exterior surface, said prosthetic valve further having a long axis passing through the centers of the circles formed by at least two circumferences of said cylindrical shape along the distance between said apex and said base, said fixation device comprising:

a) at least two expandable mounting rings, said rings being expandable from a first compressed state having a relatively small maximum transverse dimension to a second expanded state having a relatively large maximum transverse dimension, said rings expandable in a direction perpendicular to the long axis of said prosthetic valve, each of said rings being affixed to said prosthetic valve near a respective end thereof.

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44. (Withdrawn) A valve fixation device for affixing a non-flexible prosthetic valve to the interior wall of a vessel, said prosthetic valve having a generally cylindrical shape with a base, an apex, an interior surface and an exterior surface, said prosthetic valve further having a long axis passing through the centers of the circles, formed by at least two circumferences of said cylindrical shape along the distance between said apex and said base, said fixation device comprising:

a) at least one expandable mounting ring, said ring being expandable from a first compressed state having a relatively small maximum transverse dimension to a second expanded state having a relatively large maximum transverse dimension, said ring expandable in a direction perpendicular to the long axis of said prosthetic valve,

each of said ring being affixed to said prosthetic valve near a respective end thereof.

45. (Withdrawn) A valve fixation device for affixing a flexible prosthetic valve to the interior wall of a vessel, said prosthetic valve having a generally cylindrical shape with a base, an apex, an interior surface and an exterior surface, said prosthetic valve further having a long axis passing through the centers of the circles formed by at least two circumferences of said cylindrical shape along the distance between said apex and said base, said fixation device comprising: a) at least one expandable mounting ring, said ring being expandable from a first compressed state having a relatively small maximum transverse dimension to a second expanded state having a relatively large maximum transverse dimension, said ring expandable in a direction perpendicular to the long axis of, said prosthetic valve, each of said ring being affixed to said prosthetic valve near a respective end thereof.

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46. (Withdrawn) A method of repairing and replacing a stenosed cardiac valve comprising the steps of:

a) during cardiac rhythm, disrupting said cardiac valve, without completely removing said cardiac valve such

that said cardiac valve no longer functions as a valve, thereby decreasing pressure drop across said cardiac valve; and

b) implanting a prosthetic valve downstream, upstream or at said cardiac valve.

47. (Withdrawn) A method of repairing and replacing a stenosed cardiac valve comprising the steps of:

a) during cardiac rhythm, disrupting said cardiac valve, without completely removing said cardiac valve such that said cardiac valve no longer functions as a valve, thereby substantially equalizing the pressure gradient across said cardiac valve; and

b) implanting a prosthetic valve downstream, upstream or at said cardiac valve.

48. (Withdrawn) A method for enabling performance of an operation on a cardiac valve of a heart while the heart is beating, comprising the steps of:

a) placing at least one temporary valve in a flow path of blood vessel, said temporary valve being operative to effect greater antegrade flow than retrograde flow through said vessel; and

b) placing at least one temporary filter in said flowpath downstream from said cardiac valve, said filter being operative to restrict the passage of emboli while allowing blood to flow through said vessel.

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49. (Withdrawn) A method for performing an operation on a cardiac valve of a heart while the heart is beating, comprising the steps of:

- a) positioning at least one temporary valve in a flow path of blood, said temporary valve being operative to effect greater antegrade flow than retrograde flow;
- b) resecting or disrupting at least a portion of the cardiac valve; and
- c) affixing at least one prosthetic valve at, upstream or downstream from said resected cardiac valve.

In the outstanding Official Action, the Examiner:

- (1) acknowledged Applicants' election of Group 2, claims 3, 5, and 41;
- (2) rejected claims 3, 5, and 41 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention; and
- (3) rejected claims 3, 5, and 41 under 35 USC 103(a) as being unpatentable over Khosravi et al. or Barbut et al. in view of Garrison.

In response to Item 1 above, Applicants acknowledge the previous election of Group 2, claims 3, 5, and 41. Applicants also expressly reserve the right to prosecute all non-elected subject matter in related applications.

In response to Item 2 above, Applicants have now amended claims 3, 5, and 41 so as to more particularly define the present invention.

Claim 3 of the present invention is amended to replace "intravascular portion" in the preamble with -- device --. Claim 3 is also amended to more clearly define the structure of the valve means and the filter. Accordingly, claim 3 is believed to be in condition for allowance, and allowance thereof is respectfully requested.

Claim 5 of the present invention is now amended to replace "intravascular portion" in the preamble with -- device --. Claim 5 is also amended to more clearly define the structure of the valve means and the filter.

Accordingly, claim 5 is believed to be in condition for allowance, and allowance thereof is respectfully requested.

Claim 41 of the present invention is amended to replace "portion" in the preamble with -- device --. Claim 41 is amended to more clearly define the structure of the valve means and the filter. Accordingly, claim 41 is believed to be in condition for allowance, and allowance thereof is respectfully requested.

In response to Item 3 above, Applicants have now amended claims 3, 5, and 41 to further distinguish the present invention as claimed from the art of record.

Amended claim 3 of the present invention comprises a device for performing intravascular procedures, the device comprising a valve means positioned at the portion of the device adapted for placement in the flowpath of the blood vessel, and the filter positioned adjacent to the valve means at the portion of the device adapted for placement in the flowpath of the blood vessel.

Applicants believe that neither Khosravi et al., Barbut et al., nor Garrison, disclose or suggest, either

alone, or in combination with one another, the claimed device comprising the combination of a valve means and a filter positioned adjacent to one another at the portion of the device adapted for placement in the flowpath of the vessel. Applicant believes that Khosravi et al. and Barbut et al. each disclose a filter but do not teach or suggest a valve positioned adjacent to the filter at a portion of the device adapted for placement in the flowpath of the blood vessel. Applicant further believes that Garrison discloses a valve but does not teach or suggest a filter positioned adjacent to the valve at a portion of the device adapted for placement in the flowpath of the blood vessel.

Accordingly, claim 3 is believed to be in condition for allowance, and allowance thereof is respectfully requested.

Amended claim 5 of the present invention comprises a device for use in intravascular procedures, the device comprising a filter including a flowpath spanning portion positioned at the portion of the device adapted for placement in the flowpath of the blood vessel, and a valve assembly including valve elements positioned adjacent to the flowpath spanning portion of the filter at the portion of the device adapted for placement in the flowpath of the blood vessel.

Applicants believe that neither Khosravi et al., Barbut et al., nor Garrison, disclose or suggest, either alone, or in combination with one another, the claimed device comprising a filter including a flowpath spanning portion and a valve assembly positioned adjacent to one another at the portion of the device adapted for placement in the flowpath of the vessel. Applicant believes that Khosravi et al. and Barbut et al. each disclose a filter but do not teach or suggest the combination of a filter including a flowpath spanning portion and a valve assembly positioned adjacent to one another at a portion of the blood vessel. Applicant further believes that Garrison discloses a valve but does not teach or suggest the combination of a filter including a flowpath spanning portion and a valve assembly positioned adjacent to one another at a portion of the device adapted for placement in the flowpath of the blood vessel. Accordingly, claim 5 is believed to be in condition for allowance, and allowance thereof is respectfully requested.

Amended claim 41 of the present invention comprises a device for performing intravascular or intracardiac procedures, the device comprising a valve means positioned at the portion of the device adapted for placement in the flowpath of the blood vessel, and a filter positioned

adjacent to the valve means at the portion of the device adapted for placement in the flowpath of the blood vessel.

Applicants believe that neither Khosravi et al., Barbut et al., nor Garrison, disclose or suggest, either alone, or in combination with one another, the claimed device comprising the combination of a valve means and a filter positioned adjacent to one another at the portion of the device adapted for placement in the flowpath of the vessel. Applicant believes that Khosravi et al. and Barbut et al. each disclose a filter but do not teach or suggest a valve positioned adjacent to the filter at a portion of the device adapted for placement in the flowpath of the blood vessel. Applicant further believes that Garrison discloses a valve but does not teach or suggest a filter positioned adjacent to the valve at a portion of a device adapted for placement in the flowpath of the blood vessel. Accordingly, claim 41 is believed to be in condition for allowance, and allowance thereof is respectfully requested.

In the event that any additional fees may be required in this matter, please charge the same to Deposit Account No. 16-0221.

Respectfully submitted,

James A. Sheridan 7/23/03

James A. Sheridan

Registration No. 43,114

Pandiscio & Pandiscio

470 Totten Pond Road

Waltham, MA 02451-1914

Tel. No.: (781) 290-0060

KT/VIA3.AMD